UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	**[REDACTED VERSION]**

TRACK ONE DEFENDANTS' COMMENTS ON THE REPORT OF DR. ERNST R. BERNDT

Many of Dr. Berndt's observations confirm what the Track One Defendants have been saying in this case from the outset. We offer this submission to highlight those observations and to discuss their implications for class certification.

I. DR. BERNDT'S REPORT CONFIRMS THAT PLAINTIFFS' CLAIMS AS TO SELF-ADMINISTERED DRUGS CANNOT BE LITIGATED ON A CLASS-WIDE BASIS

Dr. Berndt makes a number of key findings with respect to self-administered drugs that confirm that plaintiffs' class certification motion should be denied. First, Dr. Berndt confirms that there has been widespread and varied knowledge, dating back to at least the beginning of the proposed class period, that published AWPs did not reflect average acquisition costs ("AACs") or average sales prices ("ASPs") net of chargebacks, discounts and rebates. Second, Dr. Berndt confirms that competition among PBMs is robust and confers important benefits on the industry, including third party payors. Third, with respect to generic drugs, Dr. Berndt confirms that the relationship between AWPs and ASPs for such drugs is extremely complex and variable; that this complexity and variability has been known for some time; and that such drugs are most commonly reimbursed based on proprietary MAC schedules, not AWP. These findings lead inexorably to the conclusion that plaintiffs' claims regarding self-administered drugs cannot be tried on a class-wide basis (and also have no merit).

A. Dr. Berndt Confirms That There Is Widespread and Varied Knowledge of "Spreads" on Single Source Drugs

Dr. Berndt confirms that "it has long been widely understood" that AWP is "a misnomer." (Report ¶ 14.) He acknowledges, as plaintiffs' experts have, that for many years it has been "common knowledge" that the AWP of a branded drug is typically 20% to 25% greater than WAC, the price at which manufacturers sell such drugs to wholesalers (id. ¶ 15), and that, as a result of rebates and chargebacks, health care providers can sometimes purchase at prices

below WAC. (Id.) Dr. Berndt also notes that the government has publicized the fact that AACs for pharmacies and providers are less than AWP for many years. (Id. ¶ 65.) In Appendix B to his report, Dr. Berndt cites 23 government studies, issued between 1992 and 2004, that highlight the wide variability in spreads.[1]

Significantly, Dr. Berndt states that "[t]he evolution of the AWP-WAC 'spread' for branded self-administered pharmaceuticals is . . . quite understandable, and apparently not the result of any sinister or nefarious conspiracies." (Report ¶ 23.) Indeed, he suggests that a manufacturer would find it "quite challenging if not impossible to successfully set an AWP that was only, say 2-5% above the WAC." (Id. ¶ 24.) He concludes that, even though AWPs have not reflected transaction prices since at least the 1980s, "there were no incentives for any one manufacturer to change the system pricing structure and, indeed, the incentives that did exist were perverse in that unilaterally publishing more accurate AWP prices would be unprofitable and therefore unsustainable for any one manufacturer." (Id. ¶ 29.) In other words, manufacturers did not establish the AWP reimbursement regime, and no manufacturer could unilaterally alter the 20%-25% spread between WAC and AWP. Furthermore, an industry-wide agreement to change the system would create antitrust problems. (Id. ¶ 31.)

Finally, Dr. Berndt confirms that class members' knowledge regarding AWP spread varies (Report ¶ 75), thus requiring individual inquiries. He notes that a number of deponents in this case clearly understood that spreads existed, while others have asserted that they believed AWPs were "some average of wholesale prices." (Id.)

Dr. Berndt's conclusions demonstrate that plaintiffs' claims with respect to self-administered drugs cannot be adjudicated on a class basis. See Markarian v. Connecticut Life

[1] Dr. Berndt implies that, armed with this knowledge, the government could have chosen a different reimbursement benchmark but chose not to. (Report ¶¶ 64-65.)

Ins. Co., 202 F.R.D. 60, 69 (D. Mass. 2001) (denying certification because "question of causation must be decided with regard to each purchaser in the context of the particular information" purchaser had).

B. Dr. Berndt Confirms that PBM Competition Is Robust

Dr. Berndt endorses the view, expressed by the FTC and defendants' experts,[2] that "competition among PBMs is sufficient to ensure that decision-makers have sufficient information at their disposal to make wise choices that can benefit consumers." (Report ¶ 162.) Furthermore, he does not accept Dr. Hartman's contention that PBMs are guilty of "self dealing" that increases prices. (Id. ¶ 169.) Dr. Berndt agrees that the healthy effects of PBM competition on the market for single source brands apply equally to generics, notwithstanding plaintiffs' emphasis on what they deem to be "large" spreads. (Id. ¶ 207.)

Dr. Berndt concludes that commercial information regarding common negotiable contract terms, such as rebates, "is widely dispersed." (Report ¶ 133.) This, according to Dr. Berndt, "makes it difficult for any important information to remain uncovered on a sustained basis." (Id.) He adds: "While confidentiality commitments may make the terms of a specific contract 'secret', general knowledge concerning what is negotiable and what is in the range of terms typically offered is widespread." (Id. ¶ 134.) This raises individual issues because the degree of knowledge and the rebates negotiated will vary from class member to class member.

Dr. Berndt rejects the view expressed by Dr. Hartman and others[3] that additional transparency is necessary to protect class members. (Report ¶¶ 149-55.) He cites the work of Nobel Prize winner George Stigler for the principal that "the best deal is a secret deal." (Id.

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[2] See Gaier Decl. ¶¶ 10, 32, 35, 38-39, 40-42, 46, Appendices I & J; Gaier Sur-reply Decl. ¶¶ 24-25; Navarro Decl. ¶¶ 58-59, 61; Young Decl. ¶¶ 64, 121-22, 137-38, 201.

[3] See Hartman Rebuttal Decl. ¶¶ 15(f)(i), 57(b), 62, 77(c) (citing David A. Balto, "Competitive Concerns and Pricing Transparency in the PBM Market," Update, Food and Drug Law Institute, Sept./Oct. 2003); Written Tutorial of Dr. Meredith Rosenthal at 11.

¶ 145.) Dr. Berndt states: "As long as there is little possibility of being detected . . . it will typically be profitable for the manufacturer to grant a secret discount to a large buyer who can move market share . . . . If manufacturers have reason to believe ex ante, however, that a potential purchaser is likely to report publicly and truthfully the 'secret' prices tendered to it, the manufacturers are less likely to offer 'secret' discounts in the first place." (Id. ¶ 147.) He also cites statements by payors – the purported class members – that the non-transparency of rebates enables them to negotiate better deals. (Id. ¶¶ 152, 153, 166) ("Third party payors have argued against increased price and rebate transparency.") The fact that some members of the proposed class would oppose the relief plaintiffs seek underlines the inherent conflicts in the proposed class. Finally, in concluding that greater transparency would not necessarily help payors, Dr. Berndt cites some of the same evidence cited by defendants' experts,[4] and a report by the Department of Health and Human Services finding that PBM rebates are typically beneficial because "the insurer or employer typically receives 70 to 90 percent of the rebates." (Id. ¶ 160.)

In addition, the difficulty of isolating the significance of the AWP-related pricing element of a particular PBM-third party payor relationship is highlighted by a quote Dr. Berndt includes from an analyst report. That report states that the percentage of rebates passed through to the payor "varies a great deal . . . depending on the other components of the contract between the PBM and the client." (Report ¶ 158.) Thus, plaintiffs' claims would require individualized inquiry into the particular constellation of fees paid by each payor, the amount of rebates received, as well as the type of services received. Dr. Berndt also traces the history of PBMs and concludes that the degree of vertical integration and scope of services have varied over time. (Report ¶¶ 123, 128.)

[4] Compare Report ¶¶ 154, 163 with Gaier Decl. ¶¶ 38-39, 80; and Gaier Sur-reply Decl. ¶ 21 (citing FTC's statements before the Massachusetts Alcoholic Beverages Control Commission and FTC's statements in response to state legislative proposals that would mandate public disclosure of PBM-manufacturer rebate provisions).

In short, the conclusions drawn in Dr. Berndt's report demonstrate that plaintiffs' claims cannot be litigated on a class basis. First, it will be necessary for the finder of fact to analyze, on a case-by-case basis, the interrelationship between the rebates passed through by a PBM to a particular class member and the other components of the class member's contractual relationship with the PBM to determine whether that class member was injured and, if so, by how much. As Dr. Berndt notes, "[i]f competition among PBMs is vigorous, even if the self-administered AWPIDs were artificially inflated, injury and damages to third party payors do not follow, particularly on a class-wide basis." (Report at ¶ 206.) Second, as Dr. Berndt points out, "to the extent [class members] owned and operated their own PBMs . . . third party payors would seem to me to have benefited from the allegedly fraudulent AWP scheme, and thus they would appear to face conflicts as members of the proposed class." (Id. ¶ 210.) Third, the evolution of services offered by PBMs creates a "moving target" throughout the class period. Each of these individual issues renders this case inappropriate for class treatment.

C. Dr. Berndt Confirms That There Is Widespread Knowledge Regarding the Complexity and Variability of Generic and Multisource Drug Pricing

Dr. Berndt emphasizes several important differences between single source and multisource or generic drugs that further undermine the feasibility of class adjudication with respect to this latter category of drugs. First, he notes that the relationship between AWP, WAC, and AAC is "considerably more complex" and less predictable for generics and multisource products than for self single source drugs. (Report ¶ 46.)[5] He also states that the generics market is "effectively a commodities market." (Id. ¶ 47.) As a result of the characteristics of generics,

[5] This complexity stems from the critical, inherent differences in the generic drug market that have already been chronicled in the record. Unlike a branded drug, there are perfect product substitutes for each generic, and competition therefore focuses on which generic is on the shelf when a provider reaches to fill a prescription. (Defendants' Tutorial Submission at 16.) In addition, many parties in the distribution chain have some control over whether, and which, generic is dispensed. (Young Decl. ¶ 184.)

prices fluctuate constantly, making it impossible to establish any consistent relationship between benchmarks such as AWP and WAC and transaction prices. (See Young Decl. ¶ 188.) As Dr. Berndt observes, "[t]his complexity and variability has been known for quite some time," and "the fact that AWP very substantially overstated pharmacies' actual acquisition costs for generic self-administered drugs has long been publicly available information, as has the fact that the extent of overstatement has been growing over time." (Id. ¶ 73.)

Dr. Berndt states that many payors have attempted to deal with the variability in generic pricing, and to capture the discounts available for generics, by employing MAC price lists. (Report ¶ 58.) For this reason, plaintiffs' focus on "spreads" far in excess of the spread between WAC and AWP (which are limited to the generic and multisource context) is misleading.[6] Dr. Berndt notes that MAC price lists are proprietary and not necessarily related to AWPs. (Id. ¶ 58.)[7] Moreover, as defendants demonstrated in their tutorial submission, different payors use very different methodologies to calculate MACs and, as a consequence, MAC prices vary widely. (Defendants' Tutorial Submission at 48.) Furthermore, Dr. Berndt finds that third party payors often attempt to provide incentives for dispensing generic products by deliberately paying a higher dispensing fee or using "spread" to compensate for low dispensing fees. (Report ¶¶ 51, 54.) In addition, he states that payors "have long been willing to allow pharmacies to enjoy a considerable 'spread' on generic drugs" because "whenever a generic version of a drug is dispensed instead of its brand version, the third party payor typically saves a substantial amount of money." (Id. ¶ 52.)

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[6] An example frequently cited by plaintiffs is Vepesid. As Dr. Hartman's own charts demonstrate, however, reimbursement for Vepesid more closely approximates ASP than AWP. (Hartman Rebuttal Decl. Attachment D.1.b.)

[7] In those instances when third-party payors reimburse for certain generic or multisource drugs based on AWP, the discounts off AWP are steep and Professor Berndt concludes that "one should expect variability over time in the proportion of [those] generic claims referencing AWP . . . ." Berndt Report ¶ 56; see also Young Decl. ¶¶ 196-97.

Dr. Berndt's analysis shows that a class of payors for self-administered generic and multisource drugs cannot be certified. The variability in generic and multisource pricing means that individual expectations with respect to the "spread" will differ, and some class members will have no expectations at all.[8] Furthermore, it will be difficult to determine the relationship, if any, between MAC prices and AWPs without engaging in an individualized inquiry to determine how MAC prices were established by each class member. Moreover, as defendants' submissions and Dr. Berndt's report demonstrate, the rationale for particular reimbursement amounts can depend on trade-offs with other contract terms or the payor's desire to encourage generic dispensing by providing the pharmacy with a favorable margin.

* * *

In sum, Dr. Berndt's findings about the markets for single and multi-source self-administered drugs, as well as his findings about the PBM industry, support the conclusion that, contrary to plaintiffs' position, liability and damage issues can not be calculated without reference to the individual circumstances of each class member. They also deal a fatal blow to plaintiffs' claims on the merits.

II. DR. BERNDT'S ANALYSIS DEMONSTRATES THE MANY INDIVIDUAL ISSUES CONCERNING PHYSICIAN-ADMINISTERED DRUGS

Dr. Berndt's report also highlights the numerous individual issues that must be resolved to address plaintiffs' claims with respect to physician-administered drugs. Although Dr. Berndt identifies certain structural attributes of physician reimbursement that he suggests may, in certain circumstances, make this market more vulnerable to the possibility of "mischief," that observation goes to the merits rather than to class certification and, due to page limitations, will not be addressed in this submission. More importantly for purposes of the class certification

[8] This is consistent with evidence gathered by defendants from payors. (Young Decl. ¶¶ 4-5, Exs. 1e, 1g, 1h, 1j, 1k.)

motion before the Court, the very attributes that Dr. Berndt describes in his report demonstrate that plaintiffs' claims can only be assessed on an individualized, case-by-case basis.

A. As With Self-Administered Drugs, Dr. Berndt Identifies Many Individual Inquiries Relating to Physician-Administered Drugs

i. Varied Knowledge and Expectations

Dr. Berndt concludes that "it is quite clear that knowledgeable observers understood that physicians were able to purchase many of the Medicare Part B physician outpatient drugs at acquisition costs considerably less than AWP." (Report ¶ 97.) As stated in the MedPac study referenced extensively by Dr. Berndt,[9] health plans are among these knowledgeable observers: "There is a general understanding among health plans that physicians purchase drugs at prices that are below 95% of AWP and, given that health plans prices are generally above this rate, the sale of drugs is a profit center for physicians."[10]
Indeed, an OIG study from 1992 – 10 years before this lawsuit was filed – found that "AWP is not a reliable indicator of the cost of a drug to physicians" and reported "spreads" up to AWP minus 82%.[11]

Dr. Berndt's findings therefore support defendants' contention that the determination of whether any payor was injured by the publication of allegedly fraudulent AWPs requires individualized inquiries into, inter alia, whether and to what extent each payor (a) was a "knowledgeable observer" that "understood" the "considerable" spread on physician-administered drugs, (b) considered such knowledge relevant to its reimbursement decisions, and

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[9] See, e.g., Report at footnotes 120, 123-125, 129, 140, 246.

[10] Dyckman & Associates, "Health Plan Payment for Physician-Administered Drugs," study for Medicare Payment Advisory Comm'n, Aug. 2003, No. 03-5, at 4 (attached to Written Tutorial of Dr. Meredith Rosenthal as Ex. 14.)

[11] "Physicians' Costs for Chemotherapy Drugs," DHHS Office of the Inspector General, dated November 1992, at Cover Memorandum, page 1 and Appendix III (Young Report, Volume III, Section B).

(c) would have been able to negotiate more favorable reimbursements had there been greater transparency concerning acquisition costs. Responses to these inquiries will vary significantly.

The discovery taken in this matter provides many examples that confirm Dr. Berndt's observations regarding the wide variance in payors' understanding. First, a number of payors have testified that they were aware that there was no defined or consistent relationship between a drug's AWP and provider acquisition costs. [redacted] Read with Dr. Berndt's report, this evidence

[redacted]

shows that individual payor-by-payor inquiry would be required to ascertain whether a given payor had any particular expectation as to the relationship between physicians' acquisition costs for a drug and the drug's AWP, and if so, what that expectation was.

ii. Cross Subsidization

Dr. Berndt correctly notes that, in connection with CMS' recent decision to reduce reimbursement for Medicare Part B drugs, CMS has dramatically increased fees for the administration of those drugs, "in recognition of the AWP-related cross-subsidy provided [to] physicians administering Medicare Part B drugs." (Report ¶ 96.) This cross-subsidization refers to the practice of enhancing drug reimbursement to compensate for inadequate reimbursement for physician administration costs. (Id.) In the example Dr. Berndt provides, the servicing fee was increased by over 1000%, from $5 to $57. (Id.) In its implementing regulations, CMS stated that the increase in service reimbursement would correspond to and offset the decrease in drug reimbursement for oncology drugs.[17]

Furthermore, the MedPac survey cited by Dr. Berndt demonstrates that this cross subsidization was not limited to Medicare Part B. That survey found that many commercial payors (e.g., most of the Blue Cross Blue Shield plans surveyed) based their reimbursements on the Medicare fee schedule for administrative simplicity and savings.[18] As a result, those commercial plans similarly provided enhanced drug reimbursement to subsidize the costs associated with administration of the drugs. As explained in the final report, many plans were aware of this cross subsidy and understood that if they reduced drug reimbursement, they would be required to make a corresponding increase in the servicing fee.[19]

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[17] Federal Register Vol. 69, No. 4, January 7, 2004.

[18] Dckyman & Associates, supra, at 12, 17.

[19] Dyckman & Associates, supra, at 17.

Likewise, discovery in this case has shown a pervasive understanding of cross subsidization in the private sphere [redacted] A number of health plans deposed in this matter testified they understood and factored cross subsidization into their reimbursement decisions.[21] This record demonstrates that, to assess the reasonableness of the amount paid to a physician for a drug, a contract-by-contract determination would have to be made as to the reasonableness of the associated servicing fee.

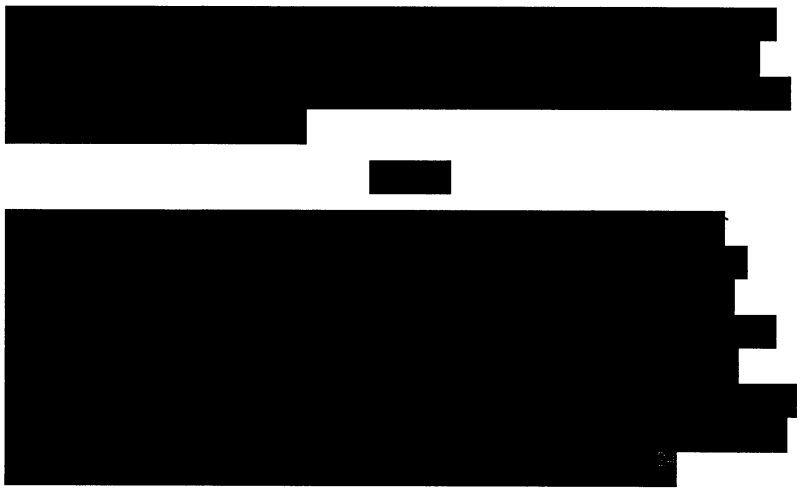
iii. Bundled Reimbursement as Part of Overall Fee Schedule[22]

Dr. Berndt states that "[t]he record in this case is unsettled to date as to whether [payments by commercial carriers] for physician-administered drugs and related services are based predominantly on AWP . . . or instead are negotiated as part of the overall physician fee schedule involving both drugs and services . . . ." (Report ¶ 98.)[23] While whether it was the universal practice may not be settled, many payors in fact negotiated physician reimbursement at the fee schedule level and made trade-offs between the elements of the schedule to secure the lowest overall reimbursement. (See Young Sur-reply Decl. § III and Attachment B [redacted]

[redacted]

[22] The Court inquired as to the state of the record on this issue during the recent argument. (2/10/05 Tr. at 29-41.)

[23] Dr. Berndt notes that plaintiffs' expert, Dr. Hartman, relies on the Dyckman & Associates study, for the proposition that payments to physicians for physician-administered drugs and related services are based predominantly on AWP. (Report ¶ 98 & n.142.) As discussed in the prior subsection, however, that study expressly acknowledges that there is an interrelationship, or cross subsidy, between reimbursement for physician-administered drugs and reimbursement for the administration of such drugs. See Dyckman & Associates, supra, at 17.



Thus, as in the self-administered context, the health plans' focus on the total reimbursement costs and their willingness to make trade-offs between drug reimbursement costs and other items necessitate a highly individualized inquiry with respect to each plan-provider contract. Moreover, as Dr. Berndt recognizes, "[a]n additional complication occurs because in those cases in which physician services and the prescribing/dispensing of physician-administered drugs are bundled into overall specialty physician fee schedules, such fee schedules will likely have geographical variations, as well as urban-rural differences, reflecting the underlying heterogeneity in real estate costs, wages for physician assistants and office staff, and the shortage/surplus supply situation among various specialties of physicians." (Report ¶ 230.)

B. Dr. Berndt Identifies Attributes Unique to Physician-Administered Reimbursement that Create the Need for Additional Individual Inquiries

Dr. Berndt identifies significant differences between the distribution and management of self-administered and physician-administered drugs (Report ¶ 186), which give rise to additional highly individualized inquiries relating to plaintiffs' claims.

i. Physicians' Unique Leverage to Negotiate Reimbursement

Dr. Berndt suggests that some specialty physicians have significantly greater leverage than pharmacies in negotiating with payors. (Report ¶¶ 107-09, 188.) Discovery in this case indicates that the relative negotiating leverage of physicians and payors has significant and varied impacts on reimbursement levels. (See Young Sur-reply Decl. ¶14 & Attachment A ¶¶ 10-23 (summarizing testimony of health plans).) In addition to the cross subsidization point discussed above, the negotiating leverage of in-demand physicians may explain why some payors are willing to allow certain physicians to profit from "spreads" on physician-administered drugs. It may also explain why many health plans have testified, as discussed above, that their focus in negotiating with physicians was to obtain the lowest overall rate possible, rather than to tie reimbursement for the drug component of the physician's services to acquisition costs.

Even within physician reimbursement, however, there are great disparities in negotiating power. Dr. Berndt notes that the negotiating leverage of some specialty physicians varies geographically. (Report ¶ 109.) This disparity in physicians' negotiating power is evidenced by the wide variation in reimbursements seen for a given physician-administered drug – as illustrated by defense experts' "scatterplots." (See, e.g., Defendants' Tutorial at 50.) In any event, Dr. Berndt's observations about physicians' negotiating leverage confirm that myriad competitive relationships among health plans and physicians must be analyzed and assessed to determine the reasons underlying the reimbursement level set in any particular instance.[25]

[25] We note that Dr. Berndt mentions that physicians' profit spread was marketed by the manufacturers of Lupron and Zoladex. (Report ¶ 107.) He notes in his report, however, that the settlements and court findings relating to those drugs were limited to situations in which physicians billed for free samples. (Id. ¶ 17). Furthermore, as Judge Woodlock instructed the jury in a criminal trial of TAP employees, discounting to physicians falls squarely within the OIG safe harbor and "physicians had no duty to reduce their charges to the government as a result of those discounts, and TAP had no duty to instruct them to do so." Jury Charge, United States v. MacKenzie, 01-CR-10350-DPW (July 9, 2004), at 51.

ii. Small Component of Medical Spend

Dr. Berndt finds that "[a]s a proportion of total spending, expenditures on physician-administered drugs have simply not been very important." (Report ¶ 187.) While that is true in terms of relative expenditures, there is substantial evidence in the record that health plans are aware of the differences between AWPs and physician's acquisition costs, and in fact negotiated and managed reimbursement for physician-administered drugs under their medical benefit plans.[26] Whether a particular payor neglected to manage or alternatively made a conscious management decision with respect to physician-administered drugs is, of course, a highly individualized inquiry.[27]

iii. Overlapping Medical and Pharmacy Benefits

Dr. Berndt notes that physician-administered drugs are sometimes reimbursed by health plans as a "pharmacy benefit" (i.e., where the PBM or pharmacy is reimbursed) and sometimes as a "major medical benefit" (i.e., where the physician is reimbursed). (Report ¶ 105.) As the article Dr. Berndt cites states, "it may often be up to the health plan to decide where the benefit falls." (Id. ¶ 105.) Although shifting reimbursement to the pharmacy benefit may result in reduced costs, Dr. Berndt recognizes that health plans may decide not to do so to avoid losing specialty physicians from their networks. (Id. ¶ 108.) As noted above, the plans' desire for

[redacted]

[27] Furthermore, as Stigler observes in "The Economics of Information," which Dr. Berndt cites in his report, the absolute amount that a buyer can save by seeking out additional information is not the issue; the amount that a buyer is willing to invest will depend on the savings that can be achieved relative to the cost of the information. (Report ¶ 146) (citing George J. Stigler, "The Economics of Information," Journal of Political Economy, 69:3, June 1961, at 216.) This suggests that if health plans are not making an effort to learn more about the cost of physician-administered drugs, it is likely that they do not perceive any cost advantage from doing so.

robust networks may enable some physicians to negotiate greater margins on the drugs they administer. Whether any particular health plan set reimbursement in a manner designed to convert physician-administered reimbursement to the pharmacy benefit or, alternatively, elected to provide a relatively high level of reimbursement under the medical benefit to maintain a robust network, is another individual inquiry that must be resolved to determine the rationale for the reimbursement set in any one instance.[28]

iv. Lack of Unique Drug Level Reimbursement Data

In his report, Dr. Berndt notes that "while self-administered drugs are managed electronically and impersonally via PBMs, for physician-administered drugs, the management is more individualized . . ." (Report ¶ 149.) He further explains that the reimbursement for physician-administered drugs generally is tracked in a manner that does not allow for the ready determination of the drug or dosage reimbursed, or which AWP, if any, was used as a basis for reimbursement. (Id. ¶¶ 193-94.) Unlike self-administered drugs that are reimbursed based on unique "NDCs," physician-administered drugs are tracked using "J-codes" that generally are not specific to a particular drug or dosage and may be composed of numerous NDCs. (Id.) As Dr. Berndt notes, "[j]ust how labor intensive crosswalking [between J-codes and NDCs] will be, and how individualized the process will need to be in order to be reliable, particularly going back in time to the 1990s, is unclear to me at this point." (Id. ¶ 197.)[29]

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[28] Health plans also may elect to provide physicians with margins to encourage the administration of certain drugs that, in the plans' view, would reduce the overall health care costs of their members (e.g., immunizations).

[29] Because one J-code usually will include multiple NDCs, physician claims cannot be linked to a specific drug's AWP. For generic physician-administered drugs, in particular, one J-code may cover all NDCs from multiple manufacturers, making it impossible to determine whether a claim billed under a J-code is related to a specific multi-source drug. Another difficulty with "crosswalking" J-codes and NDCs is that the J-code medical claims data generally does not describe: (1) which NDC was used or administered; (2) whether the reimbursement was based on a reference to AWP; and (3) if AWP is referenced, whether the parties agreed that the claim would be reimbursed below or above AWP. Furthermore, the manual process needed to "normalize" the data for J-code drugs required for analysis under Dr. Hartman's methodology is very time consuming and often requires a provider-by-provider inquiry. (Young Sur-reply Decl. ¶¶ 37-41, 44-45, Attachment C ¶¶ 10-12.)

Dr. Berndt correctly concludes that the paucity of unique drug data "creates significant difficulties in tracking physician-administered drug utilization and unit prices." (Report ¶ 194.) He also notes the "substantial likely heterogeneity in how third party payors tracked and contracted with providers" makes "questionable any generalizability of the available information." (Id. ¶ 228.) Consequently, as Dr. Hartman's own critique of the health plan data revealed, data do not exist to conduct Dr. Hartman's analysis of physician-administered drugs without undertaking significant individual inquiry. (Id. ¶ 196.)[30]

III. DR. BERNDT AGREES THAT THERE ARE SERIOUS FLAWS IN DR. HARTMAN'S METHODOLOGY

Dr. Berndt's conclusions regarding the myriad individual and subjective inquiries necessitated by plaintiffs' claims, summarized above, underscore defendants' position that causation, injury, and damages cannot be assessed using any model that purports to demonstrate knowledge, expectations, and impact on a class-wide basis. For that reason alone, certification should be denied. Moreover, Dr. Berndt's critique of the particular economic methodology proposed by plaintiffs' expert, Dr. Hartman, further shows that plaintiffs have failed to meet their burden of establishing that this case can be tried as a class action. (Report ¶¶ 201-33.)

At the outset of his discussion of Dr. Hartman's proposed methodology, Dr. Berndt expresses a critical concern left unaddressed by plaintiffs: "Since lack of competition among PBMs is crucial to Plaintiff's theory, [Dr. Berndt's and the FTC's conclusion that PBM competition is vigorous] would appear to undermine their allegations, and certainly their

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[30] In addition to having implications with respect to the predominance element of class certification, these issues also demonstrate that the proposed class will be unmanageable. Plaintiffs propose to resolve these individual issues through a proof of claim form, but have refused to provide a sample of that form. Plaintiffs cannot "mak[e] it up as they go." See, e.g., Fed. R. Civ. P. 23(c)(1)(C) (revised in 2003 to delete conditional certification); Robinson v. Texas Auto Dealers Ass'n, 387 F.3d 426 (5th Cir. 2004) (reversing certification where trial court adopted a "figure-it-out-as-we-go-along" approach). Furthermore, plaintiffs' failure to articulate how their novel theories will be tried undermines their assertion that their state law claims can be tried efficiently in a single forum. Cf. Castano v. American Tobacco Co., 84 F.3d 734, 749 (5th Cir. 1996) (noting that superiority prerequisite is not satisfied in context of an immature tort).

assumption of class-wide injury and damages" with respect to self-administered drugs. (Report ¶ 206.) This is inconsistent with Dr. Hartman's contention that all class members would pay lower prices in his "but for" world and, thus, that all class members were injured. (See Hartman Decl. ¶¶ 21-23.) As Dr. Berndt states, plaintiffs' theory of class-wide injury is only an assumption, and the facts are inconsistent with that assumption. (Report ¶ 206.)

Dr. Hartman's proposed methodology involves comparing "actual spreads" for defendants' products to "but for" spreads in order to determine the amount by which reimbursement rates were purportedly "artificially inflated" on a class-wide basis. (See Hartman Decl. ¶¶ 21-23.) Dr. Hartman's "but for" spreads are, in turn, based on "market expectations." (Id. ¶ 31.) Dr. Hartman proposes to determine market expectations "(1) by using industry-wide survey information concerning expectations regarding the relationship between AWP and ASP for drugs unaffected by the AWP scheme and/or (2) by using actual AWP and ASP data from those manufacturers and their drugs known to be unaffected by the AWP scheme." (Id. ¶ 21.) Dr. Berndt's comments regarding Dr. Hartman's methodology demonstrate that neither approach could satisfy plaintiffs' burden under Rule 23.

First, as Dr. Berndt notes and the discovery cited above demonstrates, third party payors had varying knowledge and expectations regarding AWP "spreads." Plaintiffs cannot assume away this evidence by calculating some "average" expectation based on industry-wide surveys. No class member can recover based on an average expectation that it may or may not have shared.

As to Dr. Hartman's proposal to compare the spreads for the drugs at issue in this litigation with those for drugs "known to be unaffected by the AWP scheme," Dr. Berndt notes that Dr. Hartman has failed even to identify drugs allegedly unaffected by the purported scheme.

(Report ¶¶ 213-215.) Moreover, Dr. Berndt's conclusion that it would be impossible for any single manufacturer to reduce its spreads and remain competitive (id. ¶ 24) suggests that comparative drugs do not exist.

Furthermore, Dr. Berndt correctly notes that isolating the particular factors that influenced a particular drug's "spread" requires the resolution of a host of individual issues. In Dr. Berndt's words, "[s]imply examining and recording larger differences in percent 'spreads' between each AWPID drug and 'drugs not subject to this Litigation' will not be sufficient to establish reliably that any differential 'spread' is attributable solely, partly or not at all to the alleged AWP scheme to collect inflated prescription drug payments." (Report ¶¶ 18, 212, 215.) Rather, "[o]ther factors could instead contribute to the differential 'spread', to varying extents across drugs and time." (Id. ¶ 215.) Dr. Berndt enumerates a number of those factors, including: whether the product treats an acute or chronic condition; therapeutic class; class of trade; number of competitors in the therapeutic class; generic competition; patent expiration and generic entry; side effects, efficacy and convenience profiles; substitutability with non-pharmacological treatments; over-the-counter competition; and FDA priority designation. (Id. ¶¶ 213-14.) Indeed, as Dr. Berndt notes, even if a drug that is "very similar to the AWPID drug but for its manufacturer's alleged pricing behavior" is selected, "it is likely to raise a variety of medical and clinical issues requiring expertise from medical experts, and in any case, necessitates individualized drug-specific rather than class-wide treatment." (Id. ¶ 216.) Finally, Dr. Berndt states that physician-administered drugs cannot be compared to self-administered drugs, and for that reason, Dr. Hartman's use of Lupron and Zoladex, which are physician-administered drugs, to support his conclusions with respect to self-administered drugs is "confusing and misleading." (Id. ¶ 204.)

Dr. Hartman's reliance on surveys conducted by the OIG in 1984, 1989 and 1992 comparing acquisition costs to AWPs to calculate his benchmark spreads is no substitute for his failure to identify meaningful comparative drugs. As Dr. Berndt notes, pricing in one class of trade provides little insight into pricing in other classes of trade and, indeed, "class of trade distinctions would need to be taken into account when examining the differential spreads." (Report ¶¶ 47, 219.)[31] Furthermore, instead of considering the range of discounts reflected in those reports, which in 1984 ranged from 23% to 41.78% below AWP and in 1992 ranged from 9% to 83% below AWP, Dr. Hartman based his benchmarks on averages. (Hartman Decl. ¶¶ 29-30, Attachment D ¶ 21.) Such averages, of course, inappropriately ignore the heterogeneity of discounting and rebating that occurs geographically, over time, across classes of payors, and within single classes of payors.[32]

Dr. Berndt also notes that in calculating "but for" spreads, Dr. Hartman chose to ignore later surveys and reports that reveal substantially greater spreads. (Hartman Decl. ¶ 29, Attachment D ¶ 21(c); Hartman Dep. Tr. at 44-55.) Dr. Hartman's excuse for doing so is that data are assimilated slowly and may be "contaminated to an unknown extent" by the alleged AWP scheme. (Hartman Decl. ¶ 29, Attachment D ¶ 21(d.)) Dr. Berndt rejects this conclusion with respect to self-administered drugs. (Report ¶ 222.) And, though Dr. Berndt acknowledges that data with respect to physician-administered drugs may be assimilated more slowly, he observes that Dr. Hartman's argument on this point is irreconcilable with plaintiffs' contention that AWP "works" and is not being challenged for 99% of prescriptions. (Id. ¶ 223.)

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[31] Dr. Hartman's failure to do that, and the way in which this artificially increases spreads, is a major issue raised in defendants' challenge to Dr. Hartman's methodology. (Track 1 Defendants' Mem. in Support of Motion to Strike the Declaration of Raymond S. Hartman at 13-14.) Dr. Berndt's observations on this point are consistent with defendants' position. (Report ¶¶ 47, 219.)

[32] See Report ¶ 213.

While Dr. Berndt considers whether a hedonic price analysis could result in a more sophisticated theoretical approach to the issues, he observes that Dr. Hartman has not proposed such an analysis in this case. (Report ¶¶ 217-18.) There are reasons for that. Dr. Hartman himself recognizes that a hedonic analysis is "not . . . sufficient for certification" because "[i]t still remains for the court to decide whether the measured commonalities predominate."[33] Furthermore, as Dr. Berndt points out, a hedonic approach is "problematic" where, as here, products and markets change over time. (Id. ¶ 218.) A hedonic analysis will only be reliable if it can control for all relevant product and transaction characteristics, such as payor knowledge and leverage of competition, which are not observable without individualized investigation. Although a hedonic analysis may be useful for analyzing averages, it is not useful for purposes of a class action because liability and causation cannot be established based on averages.

In sum, Dr. Berndt's observations regarding the economic methodology proposed by plaintiffs' expert strongly support defendants' position that plaintiffs have failed to demonstrate – as they are required to do – how this case could be tried on a class-wide basis. See Waste Mgmt. Holdings, Inc. v. Mowbray, 208 F.3d 288, 298 (1st Cir. 2000); Tardiff v. Knox County, 365 F.3d 1, 4-5 (1st Cir. 2004).

Respectfully submitted,

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[33] Raymond S. Hartman and Michael J. Doane, "The Use of Hedonic Analysis for Certification and Damage Calculations in Class Action Complaints," Journal of Law, Economics and Organizations, 3(2), Fall 1987, at 354.

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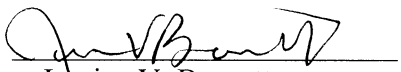
CERTIFICATE OF SERVICE

I certify that on March 11, 2005, a true and correct copy of the foregoing Track One Defendants' Comments on the Report of Dr. Ernst R. Berndt [Redacted Version] was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to Verilaw Technologies for posting and notification to all parties.



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